Remarks

Double Patenting:

Claims 13-30 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent 7,098,032. Applicants note that claim 18 was specifically not rejected as being unpatentable over U.S. Patent 7,098,032 in the office action of 12/18/06. Accordingly, Applicants incorporated the limitations of claim 18 into claim 13. The action states that claims 11-13 and 18-21 of 7,098,032 deal with making an amphipathic copolymer comprising a polycation and a polyanion. This statement is incorrect. While these claims do in fact deal with making an copolymer comprising a polycation and an polyanion, this copolymer is a *polyampholyte* (containing positive and negative charge), not *amphiphathic* (containing hydrophilic and hydrophobic parts).

Rejection of the claims under 35 USC §102:

Claims 13-22 and 25-30 have been rejected under 35 U.S.C. 102(e) as being anticipated by Meier et al (U.S. Patent 6,616,946 (946)'). The Action states that the polymers of '946 inherently possess membrane activity because a) they may contain antibodies which can bind to a cell surface molecule and b) because they are delivery vehicles which fuse to cells for delivery purposes, as replacements for liposomes. With respect to a), antibodies do not possess membrane activity as defined in the Applicants' specification. According to the Applicants' specification, the alteration of membrane structure must induce either small molecule permeability, pore formation in the membrane, a fusion and/or fission of membranes, an alteration that allows large molecule permeability, or a dissolving of the membrane; which can be shown by red blood cell lysis (hemolysis), liposome leakage, liposome fusion, cell fusion, cell lysis or endosomal release. One skilled in the art would not consider an antibody to possess any of these activities. In support of this assertion, a Declaration under 37 C.F.R. 1.132 is attached. With respect to b), the examiner is presuming facts that are neither supported or suggested in the prior art. '946 teaches a method to make hollow spheres into which an agent can be inserted. '946 states that liposomes have been used for the same reason but that they have certain limitations, such as stability. Nowhere in '946 or the available art is it suggested that their hollow particles possess the membrane fusion characteristics inherent with some, but not all liposomes. In fact, the terms fuse

and fusion are not present in '946. The inventors of '946 clearly state that their invention is a hollow particle wherein the permeability of the particle changes based on conditions. Their particle can release a encapsulated agent from within the particle, but nowhere is it suggested that the particle possesses any ability to directly affect transfer of the agent into a cell. They describe the use of their particle to release an agent in a region of a human body, but make no claim or suggestion of any ability to delivery the agent into a cell. In support, a Declaration under 37 C.F.R. 1.132 is attached.

Rejection of the claims under 35 USC §103:

Claims 23-24 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Meier et al (U.S. Patent 6,616,946) in view of Merdan et al. (Adv Drug Deliv Rev 2002). It is the Applicants' opinion that the arguments made in response to the 102(e) rejection over Meier et al. is sufficient to obviate the 103 rejection. Applicants request reconsideration of this §103 rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 13-30 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the USPTO on this date: 9/19/2007.

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